

REMARKS

Review and reconsideration of the non-final Office Action mailed April 1, 2009 (the "Office Action"), is respectfully requested in view of the preceding amendments and the following remarks. This Amendment is accompanied by credit card authorization for the Commissioner to charge the \$130 fee for a retroactive one-month extension of time. Although no fees are believed due, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 14-1437.

At the time of the Office Action, claims 15 and 7 were pending, with all claims being rejected under one or more of 35 U.S.C. §103(a) and 35 U.S.C. §112, second paragraph. By this Response, claim 5 is amended. No new matter is added.

The amendments presented herein have been made solely to expedite prosecution of the instant application to allowance and should not be construed as an indication of Applicant's agreement with or acquiescence to the Examiner's position. Accordingly, Applicants expressly maintain the right to pursue broader subject matter through subsequent amendments, continuation or divisional applications, reexamination or reissue proceedings, and all other available means. The rejections and responses thereto are set forth fully below.

Claim Rejections - 35 U.S.C. §112, Second Paragraph

In the Office Action, claim 5 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action asserts that there was some confusion regarding the overlapping limitations of claim 1 and claim 5. Claim 5 has been amended so that it is an independent claim, rather than being dependent on claim 1. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

Claim Rejections - 35 U.S.C. §103(a)

In the Office Action, claims 1-5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Canadian Patent No. 2,335,149 issued to Golz-Berner *et al.* (hereinafter “Golz-Berner”) in view of PCT No. WO 00/64472 issued to Murad, H. (hereinafter “Murad”) and U.S. Patent No. 6,652,868 issued to Simon *et al.* (hereinafter “Simon”). The Office Action asserts that Golz-Berner discloses all elements of the claims with the exception of extracts from pomegranate, rosemary, figs and peeled musk melons. The Office Action then asserts that these ingredients can be found in the secondary references and that any additional differences are merely the result of judicious selection and optimization. Applicants respectfully disagree, in part because the cited references fail to disclose several substantial claim elements and substantial unexpected results produced by the claimed anti-ageing cosmetic. In support of these arguments, Applicants submit herewith the Declaration of Co-Inventor Karin Golz-Berner Under 37 C.F.R. §1.132 (hereinafter “Golz-Berner Declaration”).

The subject matter of the claimed anti-ageing skin cosmetic as set forth in claim 1 is drawn to:

1. (original) An anti-ageing skin cosmetic comprising:
0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits;
0.1 to 3% by weight of an extract from pomegranate fruits;
0.001 to 0.5% by weight of a ground dry mixture of rosemary stems and leaves;
0.01 to 3% by weight of liposomes containing an extract from peeled musk melons;
0.1 to 5% by weight of liposomes containing a plankton extract containing the photolyase enzyme;
0.1 to 5% by weight of liposomes containing 0.1 to 0.5% by weight, in relation to the liposome weight, of a micrococcus lysate containing the UV-endonuclease enzyme; and
up to 100% by weight, other active substances, carrier substances, adjuvants or mixtures thereof, all percentages being relative to the cosmetic's total weight.

The claimed anti-ageing skin cosmetic unexpectedly produces enhanced reduction of fine wrinkles over formulations containing other combinations of the claimed ingredients. In addition, the claimed anti-ageing skin cosmetic requires a ground, dry rosemary mixture and an extract from a mixture of fig leaves and fruits. The cited reference do not disclose or suggest either of these claimed features and do not disclose or suggest the claimed anti-ageing skin cosmetic including the claimed combination of ingredients.

The Office Action asserts that Murad discloses the claimed 0.001 to 0.5% by weight of ground, dry rosemary mixture. Murad is drawn to a composition that includes a fruit extract in a pharmaceutically acceptable carrier for treating dermatological disorders. Murad, Abstract. Murad discloses that *rosemary extract, i.e., an aromatic oil*, may be included in an amount ranging from 0.5-8 wt-%, preferably 0.7 to 7 wt-%. Murad, Page 16, ln. 28; Page 18, ln. 8-11.

In contrast to the aromatic rosemary extract of Murad, the claims are drawn to ground dry mixture of rosemary stems and leaves in an amount of 0.001 to 0.5 wt-% (claim 1) or 0.001 to 0.01 wt-% (claim 5). As explained in the Specification:

Rosemary (*Rosmarinus officinalis*) is not used in the known form of an extract or oil, but as a ground dry mixture of stems and leaves. *Such a mixture surprisingly has a high free-radical-scavenging activity and therefore a very high radical protection factor (RPF).*

Specification, Paragraph [0009].

As explained in the Specification, the claimed ground, dry rosemary mixture of stems and leaves have surprisingly high RPF values compared with the aromatic oil extract disclosed by Murad. *Id.* Clearly, Murad fails to disclose both the claimed dry mixture of rosemary stems and leaves, as well as, the claimed amount of the dry rosemary mixture. As explained by Dr. Golz-Berner:

It is the interaction of the claimed ingredients, including the dry rosemary mixture, in the claimed amounts that results in the unexpectedly superior anti-ageing effect, which is discussed in Section 4. Specification, Paragraph [0036]-[0039]. ***There is nothing in Murad or the other cited references that discloses***

or suggests using the claimed dry mixture of rosemary stems and leaves in the claimed amounts.

Golz-Berner Declaration, Section 3.

The Office Action asserts that Simon discloses the claimed 0.1-5% by weight of an extract from a mixture of fig leaves and fruits. Simon is drawn to a method of epidermal peeling in a human and production of a preparation for implementation of the method. In particular, the compositions disclosed by Simon include vegetable derived elements characterized by sufficient length and rigidity to enter into the horny layer of the skin and facilitate skin resurfacing. Simon, Abstract. In other words, the vegetable derived elements are coarse fibers that provide a pumice-like function. Golz-Berner Declaration, Section 3.

Simon explains that it is possible to obtain satisfactory skin resurfacing using a multitude of vegetable derived elements of very small size, *i.e.*, 5 to 100 microns. Simon, Col. 2, ln. 29-36, 42-50 & 58-63. Simon discloses that the multitude of elements are preferably of vegetable origin and may include "the hairs that are present on the surface of *Ficus carica* leaves." Simon, Col. 3, ln. 7-17 & 28-33. The compositions disclosed in Simon contain 20 to 60 wt-%, preferably 30 to 40 wt-% of the elements of vegetable origin. Simon, Col. 5, ln. 37-43.

Taken as a whole, it is clear that Simon discloses including 20 to 60 wt-% of hairs from *Ficus carica* leaves in fiber form in order to provide a pumice-like effect. In contrast, the claims are drawn to compositions containing 0.1 to 5 wt-% of an extract from a mixture of fig leaves and fruits. As explained by Dr. Golz-Berner, "the function and mechanism of any anti-ageing effect of the 20 to 60 wt-% *Ficus carica* leave hairs in Simon is completely different than the claimed 0.1 to 5 wt-% of an extract from a mixture of fig leaves and fruits." Golz-Berner Declaration, Section 3. Simon provides no disclosure regarding any anti-ageing effect of the claimed extract as the hairs relevant to Simon serve a purely mechanical purpose, like the grit of sandpaper, rather than the chemical or biological function provided by the claimed active ingredients. Golz-Berner Declaration, Section 3.

Furthermore, Dr. Golz-Berner explains that, “[I]t is the interaction of the claimed ingredients, including the extract of fig leaves and fruits, in the claimed amounts that results in the unexpectedly superior anti-ageing effect.” Golz-Berner Declaration, Section 3. *See, also,* Specification, Paragraph [0036]-[0039]. There is nothing in Simon or the cited references to disclose or suggest using the claimed extract of fig leaves and fruits in the claimed amounts.

Dr. Golz-Berner explains that, because Simon teaches the use of *Ficus carica* leave hairs to provide a mechanical pumice-like effect, Simon provides a strong teaching away from an extract of fig leaves and fruits in the claimed amounts. Golz-Berner Declaration, Section 3. Clearly, an extract would not provide the mechanical pumice-like effect that is critical to Simon.

In summary, the claimed anti-ageing skin cosmetic exhibits a synergistically improved anti-ageing skin effect when the claimed ingredients are included with the claims amounts of (i) an extract of a mixture of fig leaves and fruits, and (ii) a ground dry mixture of rosemary stems and leaves, are present in the anti-ageing cosmetic. The cited references fail to disclose or suggest either of these feature in the claimed amounts or otherwise. Golz-Berner Declaration Section 3. In fact, Dr. Golz-Berner explains that the cited references teach away from the claimed (i) extract of a mixture of fig leaves and fruits, and (ii) ground dry mixture of rosemary stems and leaves. *Id.* Accordingly, it is clear that the cited references fail to disclose or suggest each of the claimed elements.

Objective Evidence of Non-Obviousness - Unexpected Results

If, contrary to the evidence submitted by Dr. Golz-Berner, the Examiner concludes that a *prima facie* case of obviousness has been established, Applicants submit that the objective evidence of non-obviousness in the form of unexpected result submitted by Dr. Golz-Berner and found in the Specification rebuts such a *prima facie* case of obviousness. Of particular relevance in this regard, the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir.

1987); MPEP 2145. In *In re Chupp*, the claims were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average results for other crops. *Id.* at 644. The prior art was a homolog of the claimed compound and was disclosed as being a selective herbicide for crops generally.

The Federal Circuit noted that the claimed compound's "superior activity in corn and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound provided average selective herbicidal activity for many crops and poor herbicidal activity for others. The Federal Circuit responded to this argument by concluding that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a *prima facie* case of obviousness. *Id.* at 646.

As explained by Dr. Golz-Berner, the claimed anti-ageing skin cosmetic produces unexpected anti-ageing effects with respect to the elimination of wrinkles, *e.g.*, fine lines. Golz-Berner Declaration, Section 4. As explained in the Specification:

The anti-ageing skin effect to be expected from the inventive anti-ageing skin cosmetic due to some of its constituents is by far exceeded by an overall synergistic effect. In addition, the cosmetic achieves an excellent moisture replenishment in the skin which could not be expected from the basic constituents alone.

Specification, Paragraph [0014].

With respect to the expected anti-ageing effect, Applicants note that the Golz-Berner reference is drawn to a cosmetic preparation with a high protection factor against free radicals. The composition disclosed in the Golz-Berner reference includes five "basic components" labeled (a) through (e). Golz-Berner, Page 2, ln. 26 – Page 3, ln. 11; Page 6, ln. 14-16. These basic components constituted the "association complex," which has a high radical protection factor. Golz-Berner, Page 13, ln. 35 – Page 14, ln. 15. For example, examples 1-6 include association complex compositions having radical protection factor (RPF) values for the basic components ranging from 1925 to 5600. Golz-Berner, Page 17, ln. 3 – Page 19, ln. 19.

From this it is clear that the compositions of Golz-Berner exhibited an RPF that exceeds most other skin care compositions. Thus, a substantial improvement in reduction of fine lines over the Golz-Berner reference, such as that produced by the claimed anti-ageing skin cosmetic, is indeed an impressive and unexpected result. Golz-Berner Declaration, Section 4.

As explained by Dr. Golz-Berner, “In order to quantitatively demonstrate this synergistic result, attention should be drawn to the unexpected reduction in fine lines produced by the compositions of Example 1 of the Specification and the data being submitted with this Declaration.” Golz-Berner Declaration, Section 4. The comparison of Example 1 to a control can be found in Example 3, which describes the results of consumer tests of two groups. The first group of consumers (Group 1) applied the claimed anti-ageing skin cosmetic of Example 1 to their face for four weeks. The second group of consumers (Control 1) applied the cosmetic of Example 1 without the rosemary powder or the pomegranate extract over the same period. Specification, Paragraphs [0036] and [0039]. The percentage of consumers experiencing a reduction in fine lines after 1, 2 and 3 weeks is summarized below for each of these anti-ageing skin cosmetics:

	Group 1	Control 1
After 1 week	76%	33%
After 2 weeks	81%	43%
After 3 weeks	83%	45%

Dr. Golz-Berner states that:

[I]t is clear that the combination of the claimed ingredients provides a substantially improved reduction in fine lines when compared to a composition that is identical except for the absence of the rosemary powder and pomegranate extract. *Considering the fact that those consumers in the Control 1 group were utilizing the highly active composition disclosed in the Golz-Berner reference, this level of improvement was completely unexpected to me and my co-inventors.*

Golz-Berner Declaration, Section 4.

In order to further demonstrate the synergistic improvement in reduction of fine lines produced by the claimed anti-ageing skin cosmetics, Dr. Golz-Berner submitted the following data obtained from a consumer study (Control 2) using an anti-ageing skin cosmetic containing only the rosemary powder and pomegranate extract from the Example 1 composition, *i.e.*, without the ingredients found in Control 1. Golz-Berner Declaration, Section 4.

The percentage of consumers experiencing a reduction in fine lines after 1, 2 and 3 weeks is summarized below for each of these anti-ageing skin cosmetics:

	Group 1	Control 1 (Ex. 1 w/o rosemary and pomegranate)	Control 2 (Ex. 1 with just rosemary and pomegranate)
After 1 week	76%	33%	8%
After 2 weeks	81%	43%	17%
After 3 weeks	83%	45%	17%

Golz-Berner Declaration, Section 4.

Dr. Golz-Berner analyzed this data and stated that “both Controls fall far short of the fine line reduction produced by the claimed anti-ageing skin cosmetic of Example 1.” Golz-Berner Declaration, Section 4. It should also be noted that, with the exception of the ingredients that were not included, the active ingredients and the amounts of the active ingredients used for Controls 1 and 2 were the same as those of Example 1. *Id.* Thus, the combination of the active ingredients and amounts thereof used for Control 1 and Control 2 are the same as those in Group 1. Of particular importance, Dr. Golz-Berner explained that, “*In the absence of a synergistic relationship between the ingredients, it would be expected that the percentage of individuals experiencing a reduction in fine lines using the cosmetic of Example 1 would be equal to the sum of those experiencing a reduction in fine lines using the cosmetic of Control 1 and Control 2.*”

Golz-Berner Declaration, Section 4.

For purposes of comparison, the percentage of consumers experiencing a reduction of fine lines after 1, 2 and 3 weeks for Group 1 is compared to the sum of those experiencing a reduction of fine lines for Control 1 and Control 2 in the table below:

	Group 1	Control 1 + Control 2
After 1 week	76%	41% (33% + 8%)
After 2 weeks	81%	50% (43% + 17%)
After 3 weeks	83%	52% (45% + 17%)

Golz-Berner Declaration, Section 4.

The reduction in fine lines is at least 31% greater for Group 1 than for the sum of Control 1 and Control 2 for each of the three time periods. Dr. Golz-Berner states:

Clearly, there is a synergistic effect produced when each of the claimed ingredients is combined with the others. *This synergistic effect simply is not present when the ingredients are not used together.* Furthermore, the magnitude of the increased reduction in the presence of fine lines over the composition used in Control 1 is particularly impressive considering the RFP values reported in the Golz-Berner reference.

These results clearly demonstrate an unexpected, synergistic improvement in the reduction of fine lines when the claimed combination of ingredients is utilized. Furthermore, there is nothing in the cited references, whether considered alone or in combination that discloses or suggests this unexpected synergistic result.

Golz-Berner Declaration, Section 4.

Of particular interest, the particular ingredients used in this study are the exact ingredients that are not disclosed or suggested by the cited references, *i.e.*, the extract of a mixture of fig leaves and fruits and the ground dry mixture of rosemary stems and leaves. This further demonstrates the importance of the claimed ingredients to the unexpected results and the deficiencies of the cited references.

In conclusion, Dr. Golz-Berner states that, “the claimed anti-ageing skin cosmetics unexpectedly produce a synergistically enhanced reduction in fine lines. This synergistic reduction in fine lines is substantially superior to the results produced by compositions found in

my Golz-Berner reference, which exhibited extremely high RPF values. ***Because the base material exhibits such excellent RFP values, the substantial synergistically improved anti-ageing effect is even more unexpected.***" Golz-Berner Declaration, Section 5. The Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); MPEP 2145. Accordingly, Applicants respectfully submit that the evidence of unexpected results and analysis provided by Dr. Golz-Berner establishes that the claims are non-obvious over any combination of the cited references.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned (direct line 561-838-5229 x228) if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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